IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 1:05-CV-1416
v.	:	(Judge Sylvia H. Rambo)
	:	
MERCK & CO., INC.,	:	JURY TRIAL DEMANDED
	:	
Defendant.	:	**FILED ELECTRONICALLY**
	:	

DECLARATION OF JILL M. ONDOS IN SUPPORT OF MYLAN'S OPPOSITION TO MERCK'S MOTION TO DISMISS

I, Jill M. Ondos, declare under penalty of perjury as follows:

1. I am an attorney and a member in good standing of the Bar of the Commonwealth of Pennsylvania. I am Litigation Counsel for Mylan Laboratories, Inc., which has its principal place of business in Canonsburg, Pennsylvania. Mylan Laboratories, Inc. is the parent company of Mylan Pharmaceuticals Inc.

("Mylan"), a pharmaceutical company that develops and manufactures lower-priced generic drugs for sale in the United States.

2. I submit this Declaration in opposition to Merck & Co., Inc.'s ("Merck") Motion to Dismiss Plaintiff's Complaint for lack of subject matter jurisdiction. I have personal knowledge of the facts set forth in this Declaration, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify as to the same.

Merck's Finasteride Drug Products

3. It is my understanding that Merck generated revenues for sales of finasteride that totaled nearly $500 million in 2004.

4. To date, there are no generic versions of finasteride available in the United States.

Merck's Filing of Infringement Litigation Against Dr. Reddy's

5. It is my understanding that Merck has sued Mylan's generic competitor, Dr. Reddy's Laboratories, for infringement of two of Merck's finasteride patents for Propecia®.

Mylan's Finasteride ANDA

6. Mylan has developed and filed an Abbreviated New Drug Application ("ANDA") for its own generic version of Merck's Proscar® (finasteride).

7. To date, Mylan already has devoted years and millions of dollars in: testing and developing a non-infringing generic version of its generic finasteride product; performing sophisticated bioequivalence studies to demonstrate that Mylan's generic product is a safe and effective fully-substitutable equivalent to Merck's brand-name finasteride product; and, compiling the data and information necessary to submit an ANDA for a generic finasteride product.

8. Mylan has satisfied all substantive requirements for FDA approval and is prepared to market its generic finasteride product. Mylan's ANDA includes a so-called "paragraph IV certification" certifying that Mylan's generic finasteride product would not infringe Merck's U.S. Patent Nos. 5,886,184 and 6,046,183, as well as a so-called "section (viii) statement" to Merck's U.S. Patent No. 5,942,519. Mylan also provided Merck with the required notice of its ANDA and the factual and legal basis for Mylan's paragraph IV certification.

9. As required under 21 U.S.C. § 355(j)(5)(C)(i), Mylan also extended to Merck an Offer of Confidential Access to Mylan's ANDA for the purpose of determining whether a suit for infringement can be brought. In response to that offer, Merck requested that Mylan produce confidential information from its ANDA as well as samples of Mylan's finasteride drug product.

10. Mylan in good faith complied with Merck's request, and voluntarily provided Merck with information and product samples so Merck could determine

for itself that Mylan does not infringe Merck's patents and, as a result, so inform Mylan and/or provide Mylan a covenant not to sue.

11. Despite Mylan's production of ANDA information and product samples, Merck has never informed or represented to Mylan that Mylan's finasteride product does not infringe Merck's patents. Nor has Merck provided Mylan a covenant not to sue or otherwise promised not to sue Mylan for infringement of Merck's finasteride patents.

12. Instead, Merck only has provided Mylan with a letter stating that "it is not our intention to bring suit pursuant to 35 U.S.C. 271(e)(2) within the 45 day period from service of Mylan's Notice on the patents discussed with respect to the product of the ANDA." Merck said nothing about its intentions after expiration of the 45-day period. This 45-day period has expired.

13. Mylan has offered to resolve this litigation in exchange for a stipulation of non-infringement and covenant not to sue. Merck has not responded to Mylan's offer.

Dated this 3rd day of October, 2005.

I, JILL M. ONDOS, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

JILL M. ONDOS

CERTIFICATE OF SERVICE

I, Amy D. Brody, Esq., one of the attorneys for plaintiff, hereby certify that the foregoing **Declaration of Jill M. Ondos in Support of Mylan's Opposition to Merck's Motion to Dismiss** has been served this 4th day of October, 2005 by the Court's Electronic Case Filing (ECF) system to the following:

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